

REMARKS

Claims 36 to 65 are pending in the application. No claims are amended, added or canceled herein.

Rejection Over Duan

Claims 36 to 65 stand rejected under 35 U.S.C. § 102(b) over Duan et al., U.S. Patent No. 5,725,841 (“Duan”). Applicants respectfully traverse this rejection.

In the response submitted October 25, 2005, Applicants noted that Duan does not teach the use of amino acids and amino acid derivatives *per se*, but only the use of linear, branched or cyclic *chains*, comprising between 3 and about 40 monomer units. (Duan at column 2, lines 44 to 60 and column 4, line 33.) Thus, Applicants’ position is that Duan is properly interpreted as requiring *polypeptides*, not amino acids or amino acid derivatives, as recited in the pending claims.

It is stated in the Office Action that this argument is not persuasive, because the term “derivative” as used in the instant claims does not exclude polypeptides, which are “derived” from amino acids. Indeed, the Office Action notes that the term “amino acid derivative” is not explicitly defined in the specification, implying that the term “derivative” must be interpreted to include polypeptides.

Applicants respectfully disagree. The precedent of the Court of Appeals for the Federal Circuit (CAFC) makes clear that although the words used in a claim “are generally given their ordinary and customary meaning,” the “ordinary and customary meaning” of a claim term is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). When determining what meaning a person of ordinary skill in the relevant art would attach to a particular claim term, that person “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.* at 1314; *see also Multiform Desiccants, Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998). A court, therefore, should “rely heavily on the written description for guidance as to the meaning of the claims.” *Phillips*, 415 F.3d at 1316-17. It has thus been said that “the ‘ordinary meaning’ of a claim

term is the meaning to the ordinary artisan *after reading the entire patent.*” *Id.* at 1321 (emphasis added).

Consulting the instant specification to ascertain the meaning of the term “amino acid derivative,” one sees that Applicants teach:

Suitable substances for use as the second particulate material in at least an inhaler may be selected from . . . amino acids, di-, tri-, oligo- and poly-peptides and proteins; and from physiologically acceptable derivatives, forms, salts and solvates thereof; and from mixtures thereof.

See page 13, lines 4 to 8. Dissecting this disclosure, one sees that the specification thus teaches the use of:

- amino acids, and derivatives, forms, salts and solvates thereof;
- di-peptides, and derivatives, forms, salts and solvates thereof;
- tri-peptides, and derivatives, forms, salts and solvates thereof;
- poly-peptides, and derivatives, forms, salts and solvates thereof; and
- proteins, and derivatives, forms, salts and solvates thereof.

One of ordinary skill in the art would therefore readily recognize that “derivatives” of amino acids are not di-peptides, tri-peptides, poly-peptides, or proteins, since these compounds are all identified as being separate and distinct from amino acid derivatives. Had Applicants intended that “derivatives” of amino acids include di-peptides, tri-peptides, poly-peptides, or proteins, the separate listing of these compounds would have been redundant.

Thus, Applicants respectfully submit that interpreting the term “amino acid derivative” to include poly-peptides, as is done in the Office Action, is contrary to the meaning that the ordinary artisan would ascribe to the term *after reading the entire patent.* The subject matter defined by Applicants’ claims, when properly construed, is therefore neither taught nor suggested by Duan.

Accordingly, Applicants respectfully submit that the pending claims patentably define over Duan, and request that the rejection under 35 U.S.C. 102(b) over Duan be withdrawn.

Rejection Over Clark

Claims 36, 37, 39 to 48, 50 to 52, 55 to 63 and 65 stand rejected under 35 U.S.C. § 102(e) over Clark et al., U.S. Patent No. 6,655,379 (“Clark”). Applicants again traverse this rejection.¹

Clark states that “active agent formulations suitable for use in the present invention include dry powders, solutions, suspensions or slurries for nebulization and particles suspended or dissolved within a propellant.” See col. 5, lines 62 to 65. Clark proceeds to describe, as separate and distinct embodiments, various formulations for delivering active ingredients. The embodiments prepared as *dry powder* formulations are said to include an active agent which may be combined with pharmaceutical carriers or excipients. Suitable excipients include amino acids. See col. 6, lines 37 to 56. These dry powder formulations, however, *do not contain any propellant*, as recited in the instant claims. Accordingly, Applicants again respectfully submit that none of the dry powder formulations described in Clark anticipate or render obvious the subject matter of the claims pending in the instant application.

Clark further indicates that in an alternative embodiment, the active agent may be dissolved in a propellant or particles of the active agent may be suspended in a propellant. See col. 7, lines 16 to 120. Although Clark does not further describe such systems, it makes reference to Rubsamen et al., U.S. Patent No. 5,672,581 (“Rubsamen”) as teaching suitable formulations. *Id.* Rubsamen describes formulations that include an active agent (insulin) and a propellant, and indicates that such formulations may also include an excipient. However, Rubsamen patent teaches that suitable excipients are compounds such as oleic acid and related oils having a carbon chain length in the range of about 12-30 carbons. See Rubsamen, col. 16, lines 12 to 15. These excipients are not amino acids, nor derivatives thereof. Thus neither Clark nor Rubsamen, incorporated by reference therein, describe propellant-containing formulations as recited in Applicants’ claims. Accordingly, Applicants respectfully submit that the embodiments described in Clark that comprise an active agent

¹ Applicants also note that Clark claims priority to an application filed less than three weeks earlier than the effective filing date of the instant application. Applicants expressly reserve the right to file an affidavit to antedate Clark and remove it as prior art, if the Examiner is not persuaded by Applicants’ arguments for patentability.

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dissolved or suspended in a propellant also do not anticipate or render obvious the subject matter of the pending claims.

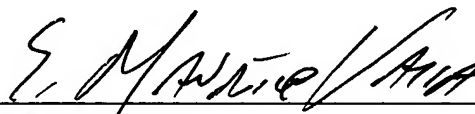
In the Office Action dated January 12, 2006, it is asserted that Clark teaches the use of formulations that utilize human serum albumin (HSA), which is asserted to be an "amino acid derivative." Applicants respectfully submit, however, that peptides and proteins are *not* amino acid derivatives, as discussed in detail above. Moreover, the disclosure of HSA-containing formulations is made only in the context of *dry powders*, not of aerosol formulations that also contain a propellant.

It is therefore Applicants position that Clark does not anticipate the pending claims. Simply put, none of the embodiments described in Clark are directed to a formulation containing an active ingredient, an amino acid (or derivative), and a propellant, as recited in the instant claims. Accordingly, Applicants respectfully request that the rejection over Clark be withdrawn.

CONCLUSION

The foregoing represents a bona fide attempt to respond to all of the pending rejections and thereby to define allowable subject matter.

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